REMARKS

Reconsideration and withdrawal of the final rejection of the claims of the above-identified application in view of the amendments and remarks presented herein is respectfully requested.

Claims 9-11 and 15 having been amended, the claims pending in the above-identified application are claims 9-11, 15 and 17.

The amendment to claims 10, 11 and 15 to recite that the plasma is administered on a daily dose of between 100-3000 or 200-1200 mg/kg of body weight of the human or animal and that the plasma mixed with powdered Crustacea or crust of Crustacea is administered at a daily dose of between 100-3000 mg/kg of body weight of the animal or human, is supported in the specification at page 6, lines 12-16.

The amendment of claim 1 to recite the animal species that are administered the swine plasma is supported at page 5, lines 17-24. These animals are non-ruminant animals.

The Examiner is urged to consider that it is improper under the present circumstances to enter a final rejection against the claims. As stated in M.P.E.P. 706.07:

> Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection. Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection.

In the present case, Applicants did not switch from one subject matter to another, thus necessitating further search. Original claim 1 contained only 26 words, and amended claim 1 contains 25. After amendment, claim 1 was still directed to a method for immunostimulation of a human or animal by administration of swine plasma. Likewise, most of the present

amendments are made in response to formal (§ 112) rejections by the Examiner. In fact, Applicants' last amendment did not even lead the Examiner to withdraw his reliance on the Suetsana et al. paper. However, the Examiner has entered a new rejection over a newly-cited pair of references, Langrehr and Stahly. While Applicants believe that the presently amended claims patentably distinguish these references, withdrawal of the finality of this rejection is manifestly appropriate and is earnestly solicited.

Response to Rejections

Claim 15 has been amended to properly space "100-3000 mg/kg," thus mooting the objection to claim 15 as set forth in paragraph 8 of the Office Action. The amendment of claims 10-11 to recite that the daily dose is mg/kg of body weight moots the rejection of claims 10-11, as set forth at paragraphs 23 and 24 of the Office Action.

The amendment to claim 9 to recite that disease resistance is increased "in a human or an animal," moots the Examiner's rejection of claims 9-10 (and 11, 15 and 17) under 35 U.S.C. § 112(2), as set forth at para. 24 of the Office Action. The amendment to claim 15 to recite that swine plasma and fine-powdered Crustacea or Crust of Crustacea is administered is supported at page 6, lines 17-18.

§102 Rejection of the Claims

Claims 9-17 were rejected under 35 U.S.C. §102(b) as anticipated by Suetsana et al. (Shokuniku ni kansuru Josei Kenkyu Chosa Seika Hokokusho, i.e, Report of the Promotional Research Investigation Results of Edible Means 10 (1991); 328-334, 1992 – English translated Document of Accession number 930121753 JICST-EPlus – Applicants' IDS). Insofar as this rejection may be maintained with respect to any of the amended claims, it is respectfully traversed.

The Examiner's only response to Applicant's lengthy and detailed analysis of this uncontrolled study is that "the instant claims only require that the administration of an immunostimulating effective amount of swine plasma to a human or an animal increase the disease resistance in said animal or human. Suetsana's method does exactly that and therefore

anticipates the instantly claimed method." Suetsana teaches no such effect of plasma ("P"). The fact that NK activity and phagacytic activity in the "P diet group" was not zero in no way evidences that the "P diet" increased these values; it may just as well decreased them, or not changed them at all. The authors do not tell us one way or another. The Examiner is directed to examine the claims from the standpoint of one of ordinary skill in the art, in possession of the available art, but without knowledge of Applicants' invention. The authors use no controls in their paper and thus, correctly, draw no conclusions about the effects of the "P diet" as compared to a diet containing no "P."

The Examiner is again requested to note that the solid fractions of animal plasma are clotting factors, globulins, including immunoglobulins, and albumin. Suetsana et al. prepare "porcine plasma-derived peptide" or "PP" by enzymatically digesting porcine plasma with pepsin, and further processing the digest by chromatography and other procedures. Casein-derived peptide is prepared from casein, a milk protein, using the same procedure. See 2.1. This procedure is similar to that used to prepare the material designated "swine plasma-derived peptide" or "PE" in the present application. See page 6. But this is not the material recited by the pending claims, which is porcine plasma or "PL" in the examples.

The Examiner is requested to consider that the point of the Suetsana et al. studies is to compare the effects of the peptides derived by enzymatic digest of porcine plasma and casein on certain immunologocial parameters, as compared with porcine plasma and casein. There are no other controls. Thus, applicants agree with the Examiner's characterization of the reference as set forth on page 5, lines 12. However applicants respectfully disagree with the Examiner's characterization of the reference as it relates to the effect of the reference substance porcine plasma.

For example, at page 5, lines 12-15, the Examiner states that Suetsana et al. disclose that "[r]ats administered with porcine plasma...showed significantly high[er] natural killer activity" (see section 3.4, Fig. 4 and page 8) and "significantly increased phagocytosis of opsonized sheep RBCs" (see section 3.6, Figure 5, page 8 and first paragraph on page 10). While porcine-plasma-derived peptide showed improved parameters as compared to porcine plasma, porcine plasma did not increase any immune function, and usually resulted in the poorest results.

In section 3.4 it is disclosed that "a significantly high NK activity was observed particularly in the PP diet group [rather] than in the P diet group (Figure 4)." Figure 4 shows that the porcine plasma P group exhibited the lowest NK activity, and that this activity was not elevated over any standard. Page 8 also discloses that "the tendency for a significantly higher [NK] activity was observed particularly in the PP diet group [rather] than in the P diet group. "Figure 5 shows that the phagocytosis of AMØ was lowest in the case of the porcine plasma diet, of all the diets tested. Page 8 discloses that the AmØ phagocytosis was high[er] in the peptide (CP, PP) diet groups than in the protein (C, P) diet groups, and a significant difference ($p<0.05$) was observed." Page 10 discloses the same results.

Thus, Suetsana does not disclose or suggest a method of increasing disease resistance in animals or humans by administering an immunostimulating amount of porcine plasma, alone or with crustacea or crustacea shells. It does not employ any controls except for the "P diet group" itself. The point of the authors' work was to study peptidyl extracts or subunits of biological materials, not to study animal plasma as a dietary supplement. One of skill in the art in possession of Suetsana et al. would be taught to digest casein or porcine plasma with pepsin to yield a peptidyl fraction that could then be used to improve the immune function of animals over that observed in animals fed a plasma or casien diet. This paper discloses no beneficial effect that the reasonably be ascribed to the "P diet." Therefore, withdrawal of this rejection is appropriate and is respectfully requested.

At pages 9-10 of the Office Action, the Examiner rejected claims 9-11 and 17 as anticipated by J.S. Langrehr et al. (U.S. Patent No. 6,156,333), "as evidenced by Stahly et al. (ISU Swine Research Report, pages 3-5 (1994)). Insofar as this rejection may be applied to any of the amended claims, it is respectfully traversed.

The Langrehr patent discloses feeding preruminant calves a feed fortifier comprising animal plasma, such as bovine or porcine plasma, together with other ingredients such as viable mutalistic bacteria, proteins, micronutrients, vitamins and the like. See Col. 3, line 20-Col. 4, line 8. At Col. 5, lines 53-62, it is disclosed that "the animal plasma may stimulate the immune system of the calf" [emphasis added]. However, it is clear from Stahly et al., that the "immunostimulatory" effect is a local effect in the g.i. tract, and does not have a systemic effect

on the immune system, as taught by Applicant. Rather, the Langrehr patent is concerned with counteracting the negative effect of feeding "hospital milk" or "low quality milk replacer" which is known to introduce pathogens into the gut of preruminant calves. See col. 3, lines 7-15.

The Examiner is further requested to note that, as amended, the present claims recite that an immunostimulating amount of swine plasma is administered to crustacea, pisces, aves, swine, horses, dogs or cats. These animals are monogastric, as are humans. Calves and other bovines are ruminant, having four separate stomach compartments. As discussed in "Rumen Development and Function in Beef Cattle," the digestive system of ruminant animals develops and functions uniquely. Therefore, as amended, the pending claims are neither disclosed nor suggested by the '333 patent. See www.cattletoday.com/archive/2000/April/Cattle_Today85.shtml (visited May 19, 2006) (copy enclosed).

To support Langrehr's theory, the Examiner sites Stahly et al. as having "taught the immunomodulating properties or impact of dietary porcine plasma on post-weaning animals by modulating the animals' susceptibility to environmental foreign antigens by activating their body immune defenses (page 3)." The Examiner's shift from the term "immunostimulating" to "immunomodulating" is significant, because Stahly et al. do not teach that spray-dried plasma stimulates the immune system in any way. Rather, Stahly et al. teaches that plasma proteins deactivate the harmful response of the pigs' immune system to environmental antigens. As explained by T.S. Stahly, "[i]t is hypothesized that plasma proteins may reduce the susceptibility of pigs to antigens and thus partially alleviate reduced growth of antigen-challenged pigs."

Thus, unlike the presently claimed process, which increases disease resistance by systemically immunostimulating non-ruminant animals, Stahly et al. teach suppressing the immune reaction of pigs to foreign antigens; that is, the immune reaction is disclosed to be a negative reaction, not a positive event, e.g., a stimulated immune system that increases disease resistance. Therefore, Stahly et al. is not logically combinable with the disclosure of the Langrehr patent, which teaches the benefits of immunstimulation in young, preruminant animals. Therefore, withdrawal of this rejection is appropriate and is respectfully requested.

CONCLUSION

Applicants respectfully request withdrawal of the final rejection and full consideration of these amendments and remarks. Alternatively, Applicants respectfully submit that the claims have been placed in condition for allowance, and therefore, entry of this amendment and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6903 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 14 day of May, 2006.

Name

Signature